

By Hand, July 11, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Vournakis et al.

Confirmation No.: To be assigned

Application No.: To be assigned

Group Art Unit: To be assigned

Filed: On even date herewith

Examiner: To be assigned

For: BIOCOMPATIBLE POLY- $\beta$ -1 $\rightarrow$ 4-N-  
ACETYLGLUCOSAMINE

Attorney Docket No.: 7867-049

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.56 and §1.97

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the continuing duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby direct the Examiner's attention to the references AA through EE which are listed on the attached revised form PTO 1449 entitled "List of References Cited by Applicant." References AA-ED are of record in the parent case; pursuant to 37 C.F.R. §1.98(d) copies of these references are not being submitted.

The above-identified patent application is a continuation of U.S. Application No. 09/866,827 ("the '827 application"), filed May 29, 2001, which is a continuation of U.S. Application No. 09/227,840 filed January 11, 1999 ("the '018 application"), which is a division of U.S. Application No. 08/471,290 filed June 6, 1995 ("the '007 application"), now issued as U.S. Patent No. 5,858,350, which is a continuation-in-part of U.S. Application No. 08/347,911, filed December 1, 1994, now issued as U.S. Patent No. 5,623,064, which is a continuation-in-part of U.S. Application No. 08/160,569, filed December 1, 1993, now issued as U.S. Patent No. 5,622,034. References AA-AG, AN-CD, and CX-CY are of record in the '007 application. References AH-AM are of record in the '018 application. References CE-CW and CE-ED are of record in the '827 application. Pursuant to 37 C.F.R. § 1.98(d), copies of the listed references AA-ED have not been included herein. Reference EE (U.S. Application No. 10/386,893) is a continuation of the '827 application; a copy is not provided as the specification is identical to that

NY2-1410702

of the '827 application. Applicants will provide copies of the references upon request by the Examiner.

Applicants respectfully request that the Examiner review the listed references and that the references be made of record in the file history of the application. Identification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application. Applicants submit herewith a revised form PTO 1449 entitled "List of References Cited" rather than "Information Disclosure Citation in an Application."

Applicants respectfully request that the Examiner review all of the references listed in the revised form PTO 1449 and that the references be made of record in the file history of the application.

Pursuant to 37 C.F.R. § 1.97(b), Applicants believe that no fee is due for filing this Information Disclosure Statement since it is being filed before the mailing date of the first Office Action. However, should the Patent Office determine that a fee is due, please charge this required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150. A duplicate of this sheet is enclosed for accounting purposes.

Date July 10, 2003

Respectfully submitted,

Laura A. Coruzzi 30,742  
Laura A. Coruzzi (Reg. No.)

By: Michael J. Ryan 41,283  
Michael J. Ryan (Reg. No.)

**PENNIE & EDMONDS LLP**  
1155 Avenue of The Americas  
New York, New York 10036-2711  
(212) 790-9090

By Hand, July 11, 2003

<b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary)				ATTY. DOCKET NO. 7867-049		APPLICATION NO. To be assigned	
				APPLICANT Vournakis et al.			
				FILING DATE Herewith		GROUP To be assigned	
<b>U.S. PATENT DOCUMENTS</b>							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,219,749	06/15/93	Bouriotis et al.			
	AB	5,008,116	04/16/91	Cahn			
	AC	3,988,411	10/26/76	Capozza			
	AD	3,989,535	11/02/76	Capozza			
	AE	5,071,977	12/10/91	Cassels et al.			
	AF	4,378,017	03/29/83	Kosugi et al.			
	AG	5,229,123	07/20/93	Masubuchi et al.			
	AH	4,532,134	7/30/85	Malette et al.			
	AI	4,605,623	8/12/86	Malette et al.			
	AJ	4,699,135	10/13/87	Motosugi et al.			
	AK	4,895,724	1/23/90	Cardinal et al.			
	AL	5,093,319	3/3/92	Higham et al.			
	AM	5,252,468	10/12/93	Fujishima et al.			
	CE	5,858,350	01/12/99	Vournakis et al.			
	CF	5,846,952	12/08/98	Vournakis et al.			
	CG	5,686,115	11/11/97	Vournakis et al.			
	CH	5,635,493	06/03/97	Vournakis et al.			
	CI	5,624,679	04/29/97	Vournakis et al.			
	CJ	5,623,064	04/22/97	Vournakis et al.			
	CK	5,622,834	04/22/97	Vournakis et al.			
	CL	6,063,911	5/16/00	Vournakis et al.			
	CM	4,575,519	3/11/86	Kifune et al.			
	CN	4,394,373	7/19/83	Malette et al.			
	CO	5,457,141	10/10/95	Matsuda et al.			
	CP	5,510,102	4/23/96	Cochrum			
	CQ	US 2002/0019367	2/14/02	Vournakis et al.			
	CR	09/875,846	6/6/01	Vournakis et al.			

	CS	US 2002-0091101	7/11/02	Vournakis et al.			
	CT	10/007,101	12/6/01	Vournakis et al.			
	CU	US 2002 0106-792	8/8/02	Vournakis et al.			
	CV	10/005,139	12/5/01	Vournakis et al.			
	CW	10/194,740	7/12/02	Vournakis et al.			
	EE	10/386,893	3/12/03	Vournakis et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	AN	WO 93/12875	07/08/93	PCT			
	AO	0543572A	05/26/93	EP			
	AP	62288602	12/15/87	JP			
	AQ	55152705	11/28/80	JP			
	AR	1,038,367	08/10/66	GB			
	CX	62288602	12/15/87	JP			X
	CY	55152705	11/28/80	JP			X
	CZ	277662	08/17/98	New Zealand			
	DA	WO 95/15343	06/08/95	PCT			
	DB	WO 93/09176	05/13/93	PCT			
	DC	WO 92/03480	03/05/92	PCT			
	DD	63-503466	12/17/87	JP-R Kohyo (Translated text of PCT application published as WO 87/07618)			
	DE	5-502267	03/19/92	JP-R Kohyo (Translated text of PCT application published as WO 92/04408)			
	DF	1-167301	07/03/89	JP-A Kokai (English abstract attached)			X
	DG	2-240101	09/25/90	JP-A Kokai (English abstract attached)			X
	DH	2-235905	09/18/90	JP-A Kokai			X
	DI	2-225539	09/07/90	JP-A Kokai (English abstract attached)			X
	DJ	2-6501	01/10/90	JP-A Kokai (English abstract attached)			X
	DK	3-204812	09/06/91	JP-A Kokai			X
	DL	3-167201	07/19/91	JP-A Kokai (English abstract attached)			X
	DM	4-126701	04/27/92	JP-A Kokai (English abstract attached)			X
	DN	4-41422	02/12/92	JP-A Kokai (English abstract attached)			X
	DO	5-271094	10/19/93	JP-A Kokai (English abstract attached)			X
	DP	5-235905	09/10/93	JP-A Kokai (English abstract attached)			X
	DQ	5-51465	03/02/93	JP-A Kokai (English abstract attached)			X
	DR	5-32702	02/09/93	JP-A Kokai (English abstract attached)			X



	DS	5-25289	02/02/93	JP-A Kokai (English abstract attached)				X
	DT	9-506126	06/17/97	JP-A Kokai (Published as WO95/15343)				X
	DU	55-152705	11/28/80	JP-A Kokai (English abstract attached)				X
	DV	56-133344	10/19/81	JP-A Kokai (English abstract attached)				X
	DW	56-131639	10/15/81	JP-A Kokai (English abstract attached)				X
	DX	58-220899	12/22/83	JP-A Kokai (English abstract attached)				X
	DY	58-88424	05/26/83	JP-A Kokai (English abstract attached)				X
	DZ	60-215003	10/28/85	JP-A Kokai (English abstract attached)				X
	EA	60-208302	10/19/85	JP-A Kokai (English abstract attached)				X
	EB	60-25003	02/07/85	JP-A Kokai (English abstract attached)				X
	EC	61-253065	11/10/86	JP-A Kokai (English abstract attached)				X

**OTHER REFERENCES** (Including Author, Title, Date, Pertinent Pages, Etc.)

AS	Aebisher, P. et al., 1993, in "Fundamentals of Animal Cell Encapsulation and Immobilization", CRC Press, pp. 197-224
AT	Austin, P.R. and Sennett, S., 1986, "Dry chitosan salts and complexes of aliphatic carboxylic acids," in "Chitin in Nature and Technology," Muzzarelli et al., eds. Plenum Press, New York, pp 279-286.
AU	Bedemeier et al., 1989, Pharm. res., 6(5), 413-417
AV	Blackwell, 1988, Meth. Enz., 161, 435-442
AW	Blackwell et al., 1967, J. Mol. Biol., 28, 383-385
AX	Davis, M. and Preston, J.F., 1981, "A simple modified carbodiimide method for conjugation of small molecular weight compounds to immunoglobulin G with minimal protein crosslinking," Anal. Biochem. 116:402-407.
AY	Domard, A., 1986, "Circular dichroism study on N-acetylglucosamine oligomers," Int. J. Macromol. 8:243-246.
AZ	Dong, C. and Rogers, J.A., 1991, Journal of Controlled Release, 17:217-224
BA	Falk et al., 1966, "Studies on chitin ( $\beta$ -(1 $\rightarrow$ 4)-linked 2-acetamido-2-deoxy-D-glucan) fibers of the diatom <i>thalassiosira fluviatilis</i> hustedt", Can. J. Chem., 44, 2269-2281
BB	Groboillot et al., 1993, "Membrane formation by interfacial cross-linking of chitosan for microencapsulation of <i>Lactococcus lactis</i> ", Biotechnology and Bioengineering 42(10):1157-1163
BC	Hirano et al., 1990, "The Regulation of Serum Cholesterol Level by Oral Administration of Chitosan in Rabbits," in Proceedings of The International Symposium on Chitin Derivatives in Life Sciences, October 5-7., pp. 115-120
BD	Hirano, S. et al., 1976, "Selective N-acylation of chitosan," Carbohydrate Research 47:315-320.
BE	Hirano, S. et al., 1981, "SEM ultrastructure studies of N-acyl- and N-benzylidene-chitosan membranes," J. Biomed. Mat. Res. 15:903-911.
BF	Hirano, S., 1989, "Production and application of chitin and chitosan in Japan," in "Chitin and Chitosan," Skjak-Braek, Anthonsen, and Sanford, eds. Elsevier Science Publishing Co., pp. 37-43.
BG	Hwang, C. et al., 1985, "Encapsulation with Chitosan: Transmembrane Diffusion of Proteins in Capsules," in Muzzarelli, R. et al., eds., "Chitin in Nature and Technology", Plenum Press, pp. 389-396
BH	Komai, T. et al., 1986, "Biomedical evaluation of acylated chitins as coating materials," in "Chitin in Nature and Technology," Muzzarelli et al., eds. Plenum Press, New York, pp 497-506.
BI	Kurita, K. et al., 1990, "Preparations of soluble chitin derivatives and the modifications to branched chitins" Polym. Prep. (Am. Chem. Soc., Div. Polym. Chem.) 31:624-625.

	BJ	Kurita, K. and Inoue, S., 1989, in "Chitin and Chitosan", Skjak-Braek et al., eds., Elsevier Science Publishing Co., Inc., p. 365-372
	BK	Maresh, G. et al., 1989, "Hydroxypropylation of chitosan," in "Chitin and Chitosan," Skjak-Braek, Anthonsen, and Sanford, eds. Elsevier Science Publishing Co., pp. 389-395.
	BL	Matthew et al., 1993, "Complex coacervate microcapsules for mammalian cell culture and artificial organ development", Biotechnol Prog 9(5):510-519
	BM	McLachlan and Craigie, 1966, Some Contemp. Stud. Mar. Sci., 511-517
	BN	McLachlan, A.G. et al, 1965, "Studies on the chitin (chitin: poly-N-acetylglucosamine) fibers of the diatom thalassiosira fluviatilis hustedt," Can. J. Botany 43:707-713.
	BO	Mireles, C. et al., 1992, in "Advances in Chitin and Chitosan", Brine, C.J. et al., eds., Elsevier Publishers, Ltd., pp. 506-515
	BP	Nishi, N. et al., 1986, "Preparation and characterization of phosphorylated chitin and chitosan," in "Chitin in Nature and Technology," Muzzarelli et al., eds. Plenum Press, New York, pp 297-299.
	BQ	Noguchi, J. et al., 1969, "Chitosan epichlorohydrin anion exchange resin with primary amine as absorption site," Kogyo Kagaku Zasshi 72:796-799.
	BR	Polk, A. et al., 1994, J. of Pharmaceutical Sciences, 83(2):178-185
	BS	Schorigin, P. and Hait, E., 1934, Chem. Ber. 67:1712-1714.
	BT	Schweiger, RG., 1972, "Polysaccharide sulfates I. Cellulose sulfate with a high degree of substitution," Carbohydrate Res. 21:219-228.
	BU	Staros, J.V., et al., 1986, "Enhancement by N-hydroxysulfosuccinate of water soluble carbodiimide mediated coupling reactions," Anal. Biochem. 156:220-222.
	BV	Thanoo et al., 1992, "Cross-linked chitosan microspheres: Preparation and evaluation as a matrix for the controlled release of pharmaceuticals", J. Pharm. Pharmacol., 44, 283-286
	BW	Tokura, S. et al., 1983, "Studies on chitin VIII. Some properties of water soluble chitin derivatives," Polym. J. 15:485-489.
	BX	US Pharmacopeia XXII, 1990, 1497-1500.
	BY	US Pharmacopeia XXII, 1990, pp. 1415-1497.
	BZ	US Pharmacopeia XXII, 1991, Supplement 5, pp. 2702-2703.
	CA	Vahouny, G.V., 1983, Journal of Clinical Nutrition, 38:278-284
	CB	Vournakis et al., 1994, "Isolation & characterization of pure poly-N-acetylglucosamine: Controlled enzymatic deacetylation and formulation for tissue engineering applications", J Cell Biochem Suppl 0, No. 18C, page 283 Abstract PZ 313, Keystone Symposium on Tissue Engineering
	CC	Yoshioke, T. et al., 1990, Biotechnol Bioeng. 35:66-72
	CD	Zielinski and Aebischer, 1994, "Chitosan as a matrix for mammalian cell encapsulation", Biomaterials 15(13):1049-1056
	ED	Translation of Japanese Office Action mailed January 8, 2002 in connection with Japanese counterpart of U.S. application no. 08/347,911, now U.S. Patent No. 5,623,064, to which the present application claims priority.

**EXAMINER****DATE CONSIDERED**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with **MPEP 609**; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.